

The opinion in support of the decision being entered today was **not** written for publication and is **not** binding precedent of the Board.

Paper No. 30

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte FRANCES S. LIGLER, BRUCE P. GABER, ANNE W. KUSTERBECK
and GREGORY A. WEMHOFF

Appeal No. 1995-4188
Application 07/860,965

HEARD: July 12, 2000

Before KIMLIN, OWENS, and WALTZ, *Administrative Patent Judges*.
OWENS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the examiner's final rejection of claims 40, 42-45, 50-53 and 56-63, and refusal to allow claim 47 as amended after final rejection. These are all of the

claims remaining in the application.

THE INVENTION

Appellants claim a flow immunosensor which contains, *inter alia*, a labeled antigen which saturates the antigen-binding sites of an immobilized antibody and is capable of being displaced by a target. Claim 40 is illustrative and reads as follows:

40. A flow immunosensor for performing a real-time analysis of a sample which is to be analyzed and which is not yet present, said flow immunosensor consisting essentially of;

an exchanger including:

a chamber having an inlet port for sample introduction and an outlet port,

a support medium, comprising a bed having a volume of 0.1 to 0.5 ml, in the chamber,

an antibody immobilized on the medium wherein the antibody recognizes with specificity and sensitivity a target,

a labelled antigen complexed to said immobilized antibody and capable of being displaced by the target, said labelled antigen saturating the antigen-binding sites of said antibody;

a detection apparatus connected to the exchanger via

the outlet port; and

a flow mean adapted for flowing liquid through the
bed at a rate of 0.1 to 2.0 ml/min, thereby providing a
target molecule in said sample insufficient time in the
vicinity of said said antigen-binding site and said labelled
antigen for equilibration.

THE REFERENCES

Gray et al. (Gray) 4,277,560 Jul. 7,
1981
Enzyme-Immunoassay 224-33, 243, 289 (Edward T. Maggio, ed.,
CRC Press 1980) (Maggio).

THE REJECTIONS

The claims stand rejected under 35 U.S.C. § 103 as
follows: claims 40, 42, 45, 50-53 and 56-63 over Maggio,¹ and
claims 43 and 44 over Maggio in view of Gray.²

¹ The examiner withdrew the rejection of claim 47 in the supplemental answer (page 4) and indicated that this claim is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

² The examiner states in the supplemental answer (page 2) that claim 46 is rejected. This claim, however, has been canceled (amendment filed October 18, 1993, paper no. 11,

OPINION

We have carefully considered all of the arguments advanced by appellants and the examiner and agree with appellants that the aforementioned rejections are not well founded. Accordingly, we reverse these rejections.

Appellants' sole independent claim (40) requires that the labeled antigen saturates the antigen-binding sites of the antibody prior to a sample being introduced into the immunosensor.

Appellants argue that Maggio discloses a competitive flow immunoassay wherein a sample is premixed with a known amount of labeled antigen and then is introduced into a column wherein any antigen in the sample competes with the labeled antigen for the available binding sites on the immobilized antibodies (brief, page 4). Appellants' claimed immunosensor, appellants argue, is a displacement flow immunoassay wherein

the antigen-binding sites of the immobilized antibodies are saturated with labeled antigen before the sample is introduced into the column, such that sample antigens must displace bound, labeled antigen from the antigen-binding sites on the immobilized antibodies in the column. *See id.*

The examiner argues that "the instant claims only claim a system with immobilized antibodies having bound labeled antigens which are clearly taught by Maggio" (answer, page 7). This is not a correct interpretation of the claims, which require that the labeled antigen saturates the antigen-binding sites of the antibody before a sample is introduced into the immunosensor.

The examiner argues that pages 224-225 of Maggio disclose labeled antigens which are complexed to an immobilized antibody, and disclose subsequent dissociation of the complex (answer,

page 7). The dissociation discussed by Maggio is dissociation of a complex which has been formed by competition between the

antigen in the sample and the labeled antigen (page 225). The dissociation renders the immunosorbent ready for another assay. See *id.* The examiner has not explained, and it is not apparent, why the relied-upon portion of Maggio is a disclosure of labeled antigen saturating the antigen-binding sites of the antibody as required by appellants' claims.

The examiner argues that Maggio's statement on page 224 that "[t]he system can also be used to perform other types of immunoassay, for example, sandwich methods and techniques that involve a second antibody bound to solid phase" describes appellants' displacement system (answer, page 7). The relevance of this portion of the reference to displacement, however, is not explained by the examiner and is not apparent.

The examiner does not rely upon Gray for any disclosure which remedies the above-discussed deficiency in Maggio.

For the above reasons, we find that the examiner has not set forth a factual basis which is sufficient for supporting a conclusion of obviousness of the invention recited in any of appellants' claims. We therefore reverse the examiner's rejections.

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DECISION

The rejections under 35 U.S.C. § 103 of claims 40, 42, 45, 50-53 and 56-63 over Maggio, and claims 43 and 44 over Maggio in view of Gray, are reversed.

REVERSED

EDWARD C. KIMLIN)	
Administrative Patent Judge)	
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)	
)	BOARD OF PATENT
TERRY J. OWENS))
Administrative Patent Judge)	APPEALS AND
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)	INTERFERENCES
)	
THOMAS A. WALTZ)	
Administrative Patent Judge)	

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